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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,026	01/18/2002	Tadashi Mukai	06854.0011	8884

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EXAMINER
JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	15

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,026	MUKAI ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- *The MAILING DATE of this communication appears on the cover sheet with the corresp ndenc address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-10,12-14,20,21,23-26 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-10,12-14,20,21,23-26 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1, 4, 7-10, 12-14, 20-21, 23-26 and 29-31 are pending in this application.

Response to Arguments

Applicant's arguments with respect to claim1-14 and 20-26 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim1, 4, 7-10, 12-14 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Takada et al. U.S. Patent No. 6,117,455.

The claims are drawn to a cilostazol preparation comprising a fine powder of cilostazol having an average particle diameter of 10 or less along with a surfactant as a dispersing and/or solubilizing agent. Dependent claims are drawn to 0.005 to 50 parts by weight based on 1 part by weight of cilostazol and specific surfactants such as polyoxyethylenesorbitan ester.

Takada et al. teach compositions comprising cilostazol (column 6, lines 18-20) in a particle size of from 1 nm to 10 μm and a polymer such as poly fatty acid esters in an amount of from 0.001% to 90% w/w (column 7, lines 44-61). Microcapsules are prepared with anionic surfactants such as polyoxyethylenesorbitan fatty acid esters and

sodium laurate. These emulsifying agents are used in a concentration of from preferably about 0,05% to about 10% w/w. (column 12, lines 8-27). Tablets and capsules of the sustained release microcapsules are recited (column 13, line 6 to column 14, line2. Although other active agents are recited, preferably the microcapsules are used for treating diseases in the circulatory system in particular thrombosis, transient cerebral ischemic attack, etc (column 14, lines 23-29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada et al. as applied to claims 1, 4, 7-10, 12-14 and 29-31 above, and further in view of Otsuka Pharmaceutical Co. LTD WO 97/48382.

The claims are drawn to a pharmaceutical composition comprising cilostazol in a fine powder of 10 μm or less and a solubilizing agent such as an alkyl sulfate, the composition being in a sustained release preparation and wherein a sustained release outer layer is released more slowly than the core.

Otsuka Pharmaceutical Co. teaches cilostazol in the form of a prolonged release drug (see abstract). Multiple-unit type prolonged release drug preparations are set forth (see examples).

Takada et al. teach compositions comprising cilostazol (column 6, lines 18-20) in a particle size of from 1 nm to 10 μm in a sustained release composition. It does not teach the sustained release composition in a multiple-unit type prolonged release drug preparation.

Takada et al. provides motivation to place cilostazol in an anionic surfactant such as polyoxyethylenesorbitan fatty acid esters and sodium laurate in a particle size of from 1 nm to 10 μm. Otsuka Pharmaceutical Co. provides motivation for one to solve the problem of the cilostazol causing side-effects such as headache, caused by the high

concentration of cilostazol released into the blood, by formulating a sustained release preparation wherein 2 small tablets are place in a sustained release preparation wherein one releases earlier than the other. Thus, by combining the teachings of Patel et al. and Otsuka Pharmaceutical Co. one would have been motivated to prepare a formulation of sustained release cilostazol with a fine particle size and an anionic surfactant.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Donna Jagoe
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614

dj
July 25, 2003